Infant and child formula shortages: now is the time to prevent recurrences

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Abstract

An acute shortage of infant formulas in the United States occurred in early 2022, exacerbating a longer-standing, less severe shortage that has occurred over the last several years. The shortage has been particularly problematic for specialized formulas such as those needed for infants and children with food allergies, intestinal failure, kidney disease, and metabolic disorders. Although undoubtedly the magnitude of the current shortage will abate over time, it has affected many children and caused tremendous distress for thousands of families. We propose a series of interventions to be undertaken as soon as feasible to help ensure that the conditions that led to this problem do not recur and families regain confidence in the safety and supply reliability of formulas for infants and young children regardless of their medical needs. *Am J Clin Nutr* 2022;116:289–292.

Introduction

Supply chain issues related to the COVID-19 pandemic led to shortages of infant formulas beginning in 2020. (1) These shortages affected all formulas and were seen in parallel to shortages in many other food and household items. Advice given to families has focused on avoiding hoarding and homemade formulas (2). Families have been encouraged to be flexible in choosing formulas and adjusting brand choices. Generally, supplies of specialized and medical formulas were not severely affected and alternate sources for these could be found when necessary.

This situation changed dramatically in February 2022, when one of the major suppliers of infant formula announced a voluntary recall of powder formula from one of its plants in Michigan. The FDA reported multiple infants with *Cronobacter sakazakii* infection that may have been related to formula produced in this factory, with 2 deaths associated with this outbreak (3). This factory ceased production of formula and as of mid-May 2022 has not resumed any production or distribution of infant formula or other enteral feeding products for infants or older children.

This major supplier of infant formula was responsible for the production of a range of formulas, notably formulas used for infants and children with severe allergies, renal failure, intestinal failure, and various metabolic disorders. For many of these formulas no alternatives were available in the United States or extremely limited supplies of alternative formulas were available but were rapidly depleted following the surge in demand. This drastic depletion in available formulas has led to a potentially catastrophic situation for thousands of infants who have lost access to specialized formulas that they need as a primary or exclusive nutritional source. The combination of both the supply chain issues and loss of a significant manufacturing facility has worsened shortages of other, more routine formulas, to the point that it can be very difficult to find even these products in many stores. Although the most substantial effects have been in the United States, other countries have also been affected by shortages of infant formula. Healthcare workers have spent large amounts of time handling multiple changes to the nutritional care of affected infants, which has likely led to large reductions in productivity and higher costs in the healthcare sector.

As of May 2022, various investigations into the formula recall are underway, with some preliminary FDA reports having been released publicly (4). However, there has been little discussion of longer-term solutions and the prevention of future critical shortages. In this perspective we consider how policy changes, in a broad sense, may be considered for implementation to prevent these types of disastrous effects of supply chain issues and formula recalls.

Recommendations

Shown in Table 1 are a list of 7 recommendations for consideration by policy makers, which are divided into 3 themes. The first theme and initial recommendation relates to providing

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TABLE 1 Critical approaches to prevent a recurrence of severe formula shortages[1]

	Approaches to prevent formula shortages
	Theme 1: Public understanding of shortages
1.	Completion and release of all investigative documents about the recall and public hearings to communicate these findings
	Theme 2: Decreasing risks of future similar events
2.	Establishment by the FDA and USDA of specific rules such that formulas identified as critical for specialized use are produced at multiple sites and preferably by multiple companies
3.	Establishment of a national plan related to assessment of formula needs and response to shortages, including those caused by natural disasters or recalls, especially in rural communities and for specialized and medical formulas. Development of this plan should include consideration of enhancing the ability to utilize formulas made by reliable international manufacturers.
4.	Creation of a database of similar formula type (e.g., amino acid–based or partial hydrolysate formulas) so that families can easily identify similar products if their usual formula is out of stock
5.	Changing of WIC rules to increase flexibility for families in purchases, with changes enacted readily when a shortage occurs, with re-evaluation of the state contracting processes of the WIC program
	Theme 3: Supporting breastfeeding families
6.	Strong advocacy for workplace and postpartum rules to enhance breastfeeding and increase time for breastfeeding at work and before return to work
7.	A national policy allowing donor milk reimbursement for families, especially when medically indicated or when specialized formulas are in short supply

[1] WIC, Women, Infants and Children (WIC) Nutrition Program.

assurance to the public that the situation that occurred has been properly investigated and resolved. The next theme, with 4 recommendations, relates to creating situations in which the formula shortages are less likely to recur. The last theme, with 2 recommendations, relates to enhancing support for breastfeeding families. We consider these 3 themes below.

First theme: Public understanding of shortages

Investigations into the formula recall are ongoing by the FDA and other agencies. Legal action is pending, as well as early efforts at investigation by Congress. Some information has been released by the FDA, and members of Congress have released limited information related to information they received related to the possible formula contamination (4).

Families have lost confidence in the safety of formulas and are increasingly frustrated by the need to search for formulas their infants and children can tolerate. Meanwhile, the extensive publicity surrounding this event has led to potentially dangerous public reactions. The most important of these is the advocacy seen on social media and elsewhere for the use of homemade, unregulated infant formulas, importation of formulas not fully reviewed by the FDA or shipped under FDA supervision, and the potential for overdilution of formula or excessively early solid food introduction to cover the formula shortfall (5). Perhaps most commonly, formulas that were not comparable to formulas under recall (or even prolonged courses of oral rehydration solutions) have been used as substitutes because of the lack of availability of formulas prescribed for specific indications by healthcare providers. Each of these reactions to the formula shortage has potentially disastrous implications for infant and child health. Combating such misinformation is made even more challenging by the lack of confidence in healthcare information occurring in society at large (6).

There should be a thorough public process to recapture public confidence in the safe production of infant and child formulas. Public hearings into the original events are an important part of this process, and these should include discussions of the supply chain issues that preceded the recall, along with full public guidance about safe formula preparation and the limited indications for using homemade formulas. The process of providing this public education should include specific funding for research into family perceptions and social media use related to infant nutrition. Active collaboration should be sought with social media providers to ensure that the disseminated information does not harm the public safety.

Second theme: Decreasing risks of future similar events

The next step is a deliberate effort to assess the fundamental challenges in the supply system that led to the shortages and take specific effective action to prevent as much as possible future recurrences. To do this, the participation of expert groups is critical, including but not limited to the American Academy of Pediatrics; the American Society for Nutrition; the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition; and the Academy of Nutrition and Dietetics. These groups must engage with key federal stakeholders such as the FDA, the CDC, and the USDA as well as Congress and the executive branch to consider both legislation and policy rulemaking in this regard. Legislative action to ensure adequate funding support via both government and private insurers for medical formulas should be a part of this discussion.

The first action that needs to be taken is to ensure that critical formulas are not produced only by a single factory in the United States and preferably not by a single company. Some of the most specialized formulas, such as metabolic formulas, are not significant income producers for companies, and as such, incentives may be needed to ensure that the supply sources are broader than one factory or company. Similar approaches have been used successfully to incentivize the discovery and production of medications for so-called orphan diseases (7).

Companies that benefit from public programs, including the Supplemental Program for Women, Infants and Children (WIC) and the Supplemental Nutrition Assistance Program (SNAP), should be obligated to develop, with the FDA and other stakeholders, a specific plan in this regard to ensure that if a factory closure occurs, substitute manufacturers can quickly be identified and/or developed.

Related to the need for additional formula suppliers in emergency situations is a broader need to assess the distribution of enteral formulas during shortages, regardless of the etiology of the shortfall, which may include natural disasters, supply chain issues, and production problems in the industry that are not necessarily due to recalls (8). A national system for parent education, not relying on individual state WIC or public health offices, is needed. Having a single or very limited number of pharmacies or groceries in a rural area as the only source of formula is inadequate, and ordering formula via the internet needs to be considered as part of this system.

A broader reassessment of the way in which formulas are marketed would be beneficial and can be overseen by nonfederal groups such as those mentioned above (American Academy of Pediatrics and others) in partnership with the FDA and Congress. We have identified a sense of confusion and at times chaos related to the marketing of formulas which is attributable to inadequately characterized terms that imply health benefits related to minor variations in lactose content or partial hydrolysis (9). This type of marketing can leave families unable to independently make needed formula switches or lacking in confidence on how to make switches when their desired formula is not available. Assessing the validity of some of these claims, notably "closest to mother's milk," can be confusing not just for families but also for pediatricians and other healthcare providers; therefore, continuing education in this regard is crucial.

During the shortages, agencies such as NASPGHAN (the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition) as well as state WIC offices have created lists detailing specific recalled formulas with the names of the most similar products (e.g., low lactose, partial whey hydrolysate, amino acid based) (10). This type of list should always be readily available, both to consumers and healthcare providers. Specific insights into the science behind the development of these products and the limitations in that science should be readily available, especially for healthcare providers.

Consideration needs to be given to the process for importation and labeling of formulas from other countries. Recently the FDA has acknowledged the possibility of allowing leniencies and flexibility in this regard from trusted sources (11). Such measures constitute a good start, but a broad, long-term approach to understanding differences are needed, such as variations in iron content between US formulas and some international formulas that cause problems with importation as well as standards for shipping and supervision of product production. The goal is to ensure that all imported formula is safely manufactured and transported across national boundaries, not to prevent such safely produced and distributed formulas from being chosen by families or providing relief in times of shortfalls.

Finally, and perhaps most challenging, the potential role of USDA-directed WIC contracting of infant formula, as it currently exists, in exacerbating shortages needs careful evaluation and further research. Currently, WIC contracts are in effect for routine formulas, with several states banding together, often one large state and several small states, in a single bidding process (12, 13). Once the bid is certified as meeting the regulations and verified as the lowest bid, WIC will almost exclusively provide this formula to its clients, although formula exceptions are allowed (e.g., postdischarge formulas for preterm infants). Although this system is efficient for the government from a cost perspective, it may lead to problems when the selected provider has a supply problem (as occurred with the current recall) and reduced levels of competition wherein a company that possesses the WIC contract in a state will often dominate shelf space and overall formula purchases in that state. WIC did respond quickly to the current recall in each state with USDA sanctioned extensions of benefits to other formulas, formula sizes, and types, but it was not instantaneous due to both constraints in regulations and technical issues in allowing formula switches.

Formulating strategies to best change this system will require input from many stakeholders, including families using these services and the USDA as well as the formula companies. Nonetheless, increased flexibility needs to be embedded in the WIC contracting system, when and if shortages develop. Facilitation of this flexibility must include participation by companies that produce durable medical equipment, which have been severely affected recently by unique challenges in maintaining supplies, filling orders, receiving, and delivering products, and communicating with end users.

Third theme: Supporting breastfeeding families

The need for additional support for breastfeeding families is well recognized and documented. This documentation includes the Surgeon General's report on breastfeeding and many other studies demonstrating the difficulties, especially in the United States, of early return to work and lack of readily available lactation support services (14). The COVID pandemic has made breastfeeding initiation more difficult, and substantial variations in rates of breastfeeding initiation and continuation plague numerous communities in the United States (15, 16). Yet, just as it is recognized that during natural disasters or conflict, support for breastfeeding is critical as part of the nutrition plan, this is also true regarding formula shortages. Families who wish to breast feed need a broad range of support in this process. Such measures will not replace resolution of the formula issues, as formula will always be needed for many infants—particularly those in need of specialized products—but lactation support should not be omitted from a comprehensive strategy to prevent the consequences of critical shortages of formula. There are relatively few situations in which breastfeeding cannot be used for infants, including some metabolic and gastrointestinal disorders. For many families, however, additional support to start or maintain breastfeeding can be beneficial in reducing the need for formula and the impact of formula shortages.

A special situation is the use of donor human milk as an alternative to infant formula. Donor milk can be helpful at a variety of stages in supporting breastfeeding. In some cases, donor milk may also be helpful in place of specialized formulas such as low-mineral formulas, because human milk is relatively lower in some minerals than infant formulas. Laws regarding payment for donor milk and its use vary by state and require a comprehensive national strategy. Encouraging human milk

donation remains a key aspect of support for the nutrition of infants and young children.

Conclusion

Severe infant formula shortages have created serious health and nutrition problems for patients and stresses for families and healthcare providers and have put many infants and young children at risk for suboptimal nutrition. Although the shortages were unanticipated, efforts on multiple fronts must be undertaken to ensure that they do not recur and that a system is developed to mitigate their effects. Such a system will require combined efforts of government and nutrition-related organizations and input from families and providers. To prevent future formula shortages, comprehensive strategies should be developed and undertaken as soon as possible and the public must be kept aware of progress.

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